

SEP 29 2005

K051698 p1/2



Merries International Inc.  
2F 3-1, Bau-Hung Rd.,  
Shin-Tien Taipei, Taiwan,

**510(k) PREMARKET NOTIFICATION  
SUMMARY OF SAFETY AND EFFECTIVENESS**

In accordance with the requirements of 21CFR 807.92

***Merries UNI-OSTEO Pellets Bone Graft Substitute***

**1. Submitted by:**

Merries International Inc.  
2F 3-1, Bau-Hung Rd.,  
Shin-Tien Taipei, Taiwan, R.O.C.  
Tel: 886-2-89117712  
Fax: 886-2-29179241  
Contact person: Jessica Li

**2. Date prepared: May 23, 2005**

**3. Trade name: Merries UNI-OSTEO Pellets Bone Graft Substitute**

**4. Product classification: Unclassified**

**5. Device product code and panel code: 87MQV/Orthopedic**

**6. Common name: Resorbable calcium salt bone void filler device (21 CFR 888.3045)**

**7. Indications for use:**

Merries UNI-OSTEO pellets are used to fill bony defects which may be surgically created voids or from traumatic injury to the bone. The product is indicated to be packed into bony defects of the skeletal system which is not intrinsic to the stability of the bony structure.

**8. Device description:**

Merries UNI-OSTEO pellets are made of calcium sulfate ( $\text{CaSO}_4$ ). These pellets dissolve safely and completely in the body in approximately 30-60 days and resorption rate corresponds with new bone growth. The product is visible on radiographs so that the implant location can be easily identified and monitored.

Merries UNI-OSTEO pellets are osteoconductive meaning that these pellets act as a scaffold and facilitate new bone growth.

1057698 1/2



Merries International Inc.  
2F 3-1, Bau-Hung Rd.,  
Shin-Tien Taipei, Taiwan,

9. **Statement of substantial equivalence:**

Merries UNI-OSTEO *Pellets Bone Graft Substitute* is substantially equivalent in base materials, function and intended use to the following devices:

- Osteoset™ Pellets (K963587, K963562)  
Manufactured by Wright Medical Technology, Inc.
- Jax™ (K010555)  
Manufactured by Smith & Nephew, Inc.

10. **Material:** The raw material, calcium sulfate, conforms to the requirements of United States Pharmacopoeia(USP) National Formulary(NF) "Official Monograph for Calcium Sulfate"

11. **Testing summary:**

- After taking into account the intended use and the device contact duration(>30days), the following biocompatibility tests have been completed and results support that Merries UNI-OSTEO is non-cytotoxic, non-sensitizing, non-mutagenic, and compatible with surrounding tissues.

Biocompatibility Tests	Results
Cytotoxicity	Pass
Intracutaneous Reactivity Test	Pass
Maximization Sensitization Test	Pass
Genotoxicity	Pass
Implantation	Pass

- Merries UNI-OSTEO has been tested of sterilization dose auditing for sterility.
- The mechanical testing showed equivalent strength to the predicate device.

Summaries and reports of all data are contained in the Premarket Notification Submission.

12. **Summary of technological characteristics:**

The device is substantial equivalence to the predicate devices based on the same material characteristics and intended use. In additional, biocompatibility tests and well documented material support its safety and effectiveness.



SEP 29 2005

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Jessica Li  
Merries International Inc.  
2F 3-1, Bau-Hung Road  
Shin-Tien, Taipei, Taiwan, R.O.C.

Re: K051698  
Trade/Device Name: Merries UNI-OSTEO Pellets Bone Graft Substitute  
Regulation Number: 21 CFR 888.3045  
Regulation Name: Resorbable calcium salt bone void filler device  
Regulatory Class: II  
Product Code: MQV  
Dated: September 8, 2005  
Received: September 8, 2005

Dear Ms. Li:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

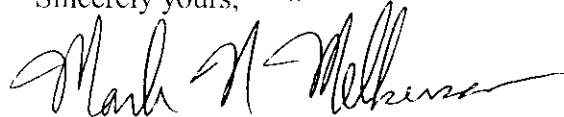
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 -Ms. Karen L. Baker

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", with a long horizontal flourish extending to the right.

Mark N. Melkerson  
Acting Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

2.3 Statement of indication for use

510(k) Number:

Device Name: **Merries UNI-OSTEO Pellets Bone Graft Substitute**

indications For Use:

Merries UNI-OSTEO pellets are used to fill bony defects which may be surgically created voids or from traumatic injury to the bone. The product is indicated to be packed into bony defects of the skeletal system which is not intrinsic to the stability of the bony structure.



(Division Sign-Off)

Division of General, Restorative,  
and Neurological Devices

510(k) Number K051698

Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF  
NEEDED)

---

Concurrence of CDRH, Office of Device Evaluation(ODE)

Page 1 of 1